REMARKS

Initially, Applicants would like to express appreciation to the Examiner for the detailed Official Action provided.

Upon entry of the above amendment, claims 1, 7, and 14-17 will have been amended. Accordingly, claims 1, 3-7, and 10-17 are currently pending. Applicants respectfully request reconsideration of the outstanding rejections and allowance of claims 1, 3-7, and 10-17 in the present application. Such action is respectfully requested and is now believed to be appropriate and proper.

Claims 1, 4-7, and 10-17 have been rejected under 35 U.S.C. § 103(a) as being unpatentable over REDDING (U.S. 2002/0156415) in view of TALISH et al. (U.S. 7,211,060) and HIDAKA et al. (U.S. Patent No. 4,990,340).

Although Applicants do not necessarily agree with the Examiner's rejection of claims 1, 7, and 14-17 on this ground, nevertheless, Applicants have amended independent claim 1 to clearly obviate the above noted ground of rejection in order to expedite prosecution of the present application. In this regard, Applicants note that REDDING, TALISH et al., and HIDAKA et al. fail to teach or suggest the subject matter claimed in amended claims 1, 7, and 14-17. Independent claim 1, as amended, sets forth an ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles including, inter alia, an irradiation unit including a first ultrasonic transducer and a second ultrasonic transducer; and a control unit that controls irradiation conditions of the irradiation unit; "wherein the control unit controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz to whiten skin or reduce skin wrinkles". Independent claim 7 sets forth "an ultrasonic percutaneous penetration kit, which, upon allowing a medicine containing an active ingredient to penetrate an organism from a skin

surface, allows vibration of ultrasonic waves to penetrate the organism from the skin surface to whiten skin or reduce skin wrinkles" including, inter alia, a medicine containing an active ingredient; an irradiation unit including a first ultrasonic transducer and a second ultrasonic transducer; and a control unit; "wherein the control unit controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz to whiten skin or reduce skin wrinkles". Independent claim 14 sets forth "A method of using an ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles" including, inter alia, "simultaneously as a medicine containing an active ingredient is made in contact with the skin, applying ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface through the medicine to whiten skin or reduce skin wrinkles". Independent claim 15 sets forth "A method of using an ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles" including, inter alia, "after a medicine containing an active ingredient has been made in contact with the skin, applying ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface through a medium that transmits ultrasonic waves to whiten skin or reduce skin wrinkles". Independent claim 16 sets forth "A method of using an ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles" including, inter alia, "after having applied ultrasonic waves having a frequency of not less than 0.5 MHz to a skin surface to whiten skin or reduce skin wrinkles, a medicine containing an active ingredient is made in contact with the skin to which the ultrasonic waves have penetrated". Independent claim 17 sets forth "A method of using an ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles" including, inter alia, "selecting two or more processes from the following three processes: a process in which a medicine containing an active ingredient is made in contact with the skin; a process in which ultrasonic waves having a frequency of not less than 0.5 MHz are applied to the

skin surface to whiten skin or reduce skin wrinkles; and a process in which, simultaneously as the medicine containing an active ingredient is made in contact with the skin, ultrasonic waves having a frequency of not less than 0.5 MHz are applied to the skin surface through the medicine to whiten skin or reduce skin wrinkles".

This amendment is fully supported by the specification, including the claims and drawings, and no prohibited new matter has been added.

Applicants' claimed method and device include improvements and advantages over the prior art. In this regard, Applicants' claimed ultrasonic percutaneous penetration device and method may be operated and used to whiten the skin. In this regard, the ultrasonic conditions of Applicants' device and method may be set according to desired target effects. To achieve skin whitening effects, melanin in the skin base layer that forms a shallow portion of the organism 2 is a target to which the active ingredient is applied. In this case, since the target is in a shallow portion from the skin surface 2a, the medicine 1 is allowed to effectively penetrate by using ultrasonic waves having a high frequency (3 to 7 MHz). To achieve skin wrinkle reducing effects, the skin corium is a target to which the active ingredient is applied. In this case, the medicine 1 is allowed to effectively penetrate by using ultrasonic waves having an intermediate frequency (1 to 3 MHz). Further, to achieve slimming effects, fat tissues and muscle layers, located at deeper portions in the organism 2, are targets to which the active ingredient is applied. The medicine 1 is allowed to effectively penetrate by using ultrasonic waves having a low frequency (0.5 to 2 MHz, preferably, 0.7 to 1 MHz) into a deep portion thereof. See particularly pages 10-11 of the instant specification.

In this manner of the operation of the ultrasonic device and method, the radiation conditions of ultrasonic waves are used to provide effective penetration of the medicine 1.

Therefore, the ultrasonic percutaneous penetration device and method of the instant invention is capable of generating ultrasonic waves having a frequency from 0.5 to 5 MHz. The frequency of the ultrasonic waves can be appropriately set within this range to achieve the desired effects.

The REDDING publication discloses an ultrasonically enhanced substance delivery system that delivers a dose of a drug through a patient's skin. As described in paragraph [0043], the REDDING device includes a control unit that may control the drug quantity delivered, the time interval and duration of drug delivery, and the frequency and intensity of the waves emitted by the transducer. As described in paragraphs [0071] – [0072], the REDDING device may be used to deliver common pharmaceutical or nutritional compounds.

As recognized by the Examiner, REDDING fails to teach or suggest controlling the frequency of the ultrasonic waves within a range from 3 to 7 MHz. Further as recognized by the Examiner, REDDING fails to teach or suggest the method of using an ultrasonic percutaneous delivery device to perform the cosmetic treatment of whitening the skin or reducing skin wrinkles, as claimed in amended independent method claims 14-17.

Further, while REDDING discloses a control unit that can control the drug quantity delivered, the time interval and duration of drug delivery, and the frequency and intensity of the waves emitted by the transducer, in the delivery device, REDDING fails to teach or suggest a control unit that controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHZ to whiten skin or reduce skin wrinkles. Thus, Applicants submit that REDDING fails to teach or suggest an ultrasonic percutaneous penetration device and kit to whiten skin or reduce skin wrinkles, including a control unit that controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz to whiten skin or reduce skin wrinkles, as set forth in amended independent claims 1 and 7.

The TALISH et al. patent is directed to an ultrasonic bandage to accelerate the healing of wounds, such as abrasions, lacerations, incisions, and ulcers, by generating ultrasonic pulses. The TALISH et al. device generates ultrasonic pulses in the range of about 20 kHz to about 10 MHz, or preferably, from 0.5-5 MHz, to promote the healing of wounds.

As recognized by the Examiner, TALISH et al. fails to teach or suggest the method of using an ultrasonic percutaneous delivery device to perform the cosmetic treatment of whitening the skin or reducing skin wrinkles, as claimed in amended independent method claims 14-17.

Further, while TALISH et al. discloses an ultrasonic transducer that can control the ultrasonic pulses, TALISH et al. fails to teach or suggest a control unit that controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHZ to whiten skin or reduce skin wrinkles. Thus, Applicants submit that TALISH et al. fails to teach or suggest an ultrasonic percutaneous penetration device and kit to whiten skin or reduce skin wrinkles, including a control unit that controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz to whiten skin or reduce skin wrinkles, as set forth in amended independent claims 1 and 7.

The HIDAKA et al. patent discloses a sustained release pharmaceutical preparation for delivering drugs through a patient's skin.

As recognized by the Examiner, HIDAKA et al. fails to teach or suggest the method of using an ultrasonic percutaneous delivery device to perform the cosmetic treatment of whitening the skin or reducing skin wrinkles, as claimed in amended independent method claims 14-17.

Further, HIDAKA et al. fails to teach or suggest a device or method for providing ultrasonic waves to the preparation. Accordingly, HIDAKA et al. fails to teach or suggest a control unit that controls the frequency of the ultrasonic waves to a frequency within a range

from 3 to 7 MHZ to whiten skin or reduce skin wrinkles. Thus, Applicants submit that HIDAKA et al. fails to teach or suggest an ultrasonic percutaneous penetration device and kit to whiten skin or reduce skin wrinkles, including a control unit that controls the frequency of the ultrasonic waves to a frequency within a range from 3 to 7 MHz to whiten skin or reduce skin wrinkles, as set forth in amended independent claims 1 and 7.

Therefore, the TALISH et al. and HIDAKA et al. patents fails to cure the deficiencies of the REDDING device, and even assuming, arguendo, that the teachings of REDDING, TALISH et al., and HIDAKA et al. have been properly combined, Applicants' claimed ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles including a control unit that controls the frequency of ultrasonic waves to whiten skin or reduce skin wrinkles as set forth in amended claims 1 and 7, and method of using an ultrasonic percutaneous penetration device to whiten skin or reduce skin wrinkles including applying ultrasonic frequency to whiten skin or reduce skin wrinkles as set forth in amended claims 14-17, would not have resulted from the combined teachings thereof.

Further, there is nothing in the cited prior art that would lead one of ordinary skill in the art to make the modification suggested by the Examiner in the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 103(a) over REDDING in view of TALISH et al. and HIDAKA et al. Thus, the only reason to combine the teachings of REDDING, TALISH et al., and HIDAKA et al. results from a review of Applicants' disclosure and the application of impermissible hindsight. Accordingly, the rejection of claims 1, 7, and 14-17 under 35 U.S.C. § 103(a) over REDDING in view of TALISH et al. and HIDAKA et al. is improper for all the above reasons and withdrawal thereof is respectfully requested.

Applicants submit that dependent claims 3-6 and 10-13, which are at least patentable due to their dependency from claims 1 and 7 for the reasons noted above, recite additional features of the invention and are also separately patentable over the prior art of record based on the additionally recited features.

Accordingly, Applicants respectfully request reconsideration and withdrawal of the rejection, and an early indication of the allowance of claims 1, 3-7, and 10-17.

SUMMARY AND CONCLUSION

In view of the foregoing, it is submitted that the present response is proper and that none of the references of record, considered alone or in any proper combination thereof, anticipate or render obvious Applicants' invention as recited in claims 1, 3-7, and 10-17. The applied references of record have been discussed and distinguished, while significant claimed features of the present invention have been pointed out.

Accordingly, consideration of the present response, reconsideration of the outstanding Official Action, and allowance of all of the claims in the present application are respectfully requested and now believed to be appropriate.

Applicants have made a sincere effort to place the present application in condition for allowance and believe that they have now done so.

Any amendments to the claims which have been made in this amendment, which do not narrow the scope of the claims, and which have not been specifically noted to overcome a rejection based upon the prior art, should be considered cosmetic in nature, and to have been made for a purpose unrelated to patentability, and no estoppel should be deemed to attach thereto.

Should the Examiner have any questions, the Examiner is invited to contact the undersigned at the below-listed telephone number.

Respectfully Submitted,
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